REMARKS

Claims 1, 7, 8, 12, 13, 15-18, and 20-24 are currently pending in the application. Claims 1 and 12 are in independent form.

The Office Action held that the previously submitted oath or declaration was defective. A properly executed oath or declaration that is signed in compliance with 37 CFR 1.67(a) is enclosed herewith. Reconsideration of the objection is respectfully requested.

The specification was objected to because it was missing pages 94-99 and that the specification includes nonsensical text block characters. Enclosed herewith are the missing pages, which pages contain DNA sequence information. Furthermore, the specification has been amended (pages 7, 16, 24, 60, 70-73, 75, 76, 78, 85, 87-89, and 91) to correct the nonsensical text block characters to their proper symbols. Reconsideration of the objection is respectfully requested.

Claim 12 stands objected to as being ungrammatical. The Office Action has held that claim 12 includes a grammatical error. Claim 12 has been amended to correct the grammatical error and reconsideration of the rejection is respectfully requested.

Claim 14 stands rejected under 35 USC 112, first paragraph, as failing to comply with the written description requirement. In particular, the Office Action states that the specification fails to provide adequate guidance as to what is a pharmacologically effective amount of a biologically active moiety. In order to further prosecution claim 14 has been canceled without prejudice thereby rendering the present rejection moot. Reconsideration of the rejection is respectfully requested.

Claims 1, 3, 7-18, 20-22, and 24 stand rejected under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Office Action has held that the phrase "administering cells" in claim 1 is unclear as to what method steps are involved. Claim 1 has been amended to recite "administering Sertoli cells to a patient" to indicate to a person having ordinary skill in the art that such cells can be used to produce a desired pharmacologically effective amount of the biologically active moiety for the patient in vivo. A person having ordinary skill in the art would readily recognize multiple local or systemic administration methods, several of which are described in the specification paragraph bridging pages 20 and 21, as acceptable forms of administration. For example, the administration methods can include, but are not limited to, subcutaneous, intravenous, intraperitoneal, intramuscular, or surgical implantation. Since the claim has been amended to more specifically recite the step involved, reconsideration of the rejection is respectfully requested.

The Office Action has held that claims 7 and 8 are indefinite. In order to further prosecution, the claims have been canceled without prejudice thereby rendering the present rejection moot. Reconsideration of the rejection is respectfully requested.

The Office Action rejects claim 12 as indefinite because the phrase "said biologically active moiety" has no antecedent basis. Claim 12 has been amended, to provide proper antecedent bases. Additionally, the recitation of "amounts" has been amended to recite "amount". Reconsideration of the rejection is respectfully requested.

The Office Action rejects claims 13 and 14 as being indefinite. The Office Action has held that the term "naturally" is unclear. In order to further prosecution, claim 13has been amended to recite "endogenous" instead of "naturally". The term "endogenous"is readily recognized by a person of skill in the art as defining expression that originates within the cell, notwithstanding the

genetic modification. Thus, claim 13 refers to cells where the genetic modification expresses a biologically active moiety not expressed in the cell prior to the genetic modification. Claim 14 has been canceled without prejudice and reconsideration of the rejection is respectfully requested.

Further, the Office Action has suggested that the preamble of claim 22 be amended from "method" to recite a "composition", since it is dependent on the composition of claim 12. Reconsideration of the rejection is respectfully requested.

Claims 1, 7-18, 20-22, and 24 stand rejected under 35 USC 112, first paragraph, because the specification, while being enabling for methods of providing a biologically active moiety in vivo by implanting Sertoli cells that have been isolated and modified in a laboratory apparatus so as to express the biologically active moiety in pharmaceutically effective amounts in vovo does not reasonably provide enablement for such methods using any other type of naturally immune privileged cells. The claims have been amended to recite "Sertoli cells" and not immune privileged cells" thereby rendering the present rejection moot. Reconsideration of the rejection is respectfully requested.

Claim 1, 8, 9, 11-13, 15, and 20-22 stand rejected under 35 U.S.C. § 102(b) as being anticipated by the Culver et al reference (PNAS 88, 3155, 1991). Reconsideration of the rejection under 35 U.S.C. § 102(b), as anticipated by the Culver et al reference, as applied to the claims is respectfully requested. Anticipation has always been held to require absolute identity in structure between the claimed structure and a structure disclosed in a single reference.

In Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 231 U.S.P.Q. 81 (Fed. Cir. 1986) it was stated: "For prior art to anticipate under §102 it has to meet every element of the claimed invention."

In Richardson v. Suzuki Motor Co., Ltd., 868 F.2d 1226, 9 U.S.P.Q.2d 1913 (Fed. Cir. 1989) it was stated: "Every element of the claimed invention must be literally present, arranged as in the claim."

The Office Action has held that the Culver et al reference teaches a method of genetically modifying mouse T lymphocytes with a retroviral expression construct encoding human adenosine deaminase (hADA). The Culver et al reference does not disclose the use of Sertoli cells and there is no disclosure in the Culver et al reference that the T cells can be used interchangeably with Sertoli cells. The presently pending independent claims have been amended to recite use of "Sertoli cells" instead of "immune privileged cells". Since the Culver et al reference does not disclose the use of Sertoli cells as recited in the presently pending independent claims, the claims are patentable of the Culver et al reference and reconsideration of the rejection is respectfully requested.

Claim 1, 3, 7, 12, 13, 15, 18, 20-22, and 24 stand rejected under 35 U.S.C. § 102(b) as being anticipated by the Builder et al patent (US Patent 5,451,660). Reconsideration of the rejection under 35 U.S.C. § 102(b), as anticipated by the Builder et al patent, as applied to the claims is respectfully requested. Anticipation has always been held to require absolute identity in structure between the claimed structure and a structure disclosed in a single reference.

The Office Action has held that the Builder et al. patent discloses use of immunoprivileged cells in vitro, but that there is no disclosure or suggestion for such useage in vivo. The presently pending independent claims have been amended to recite that the Sertoli cells are administered to a patient. The amended language indicates to a person having ordinary skill in the art that such cells are to produce a desired pharmacologically effective amount of the biologically active moiety for the patient in vivo. Since the Builder et al. patent neither discloses nor suggests the use of Sertoli cells in vivo, the presently pending independent claims are patentable over the Builder et al. patent and reconsideration of the rejection is respectfully requested.

The remaining dependent claims not specifically discussed herein are ultimately dependent upon the independent claims. References as applied against these dependent claims do not make up for the deficiencies of those references as discussed above. The prior art references do not disclose the characterizing features of the independent claims discussed above. Hence, it is respectfully submitted that all of the pending claims are patentable over the prior art.

In view of the present amendment and foregoing remarks, reconsideration of the rejections and advancement of the case to issue are respectfully requested.

The Commissioner is authorized to charge any fee or credit any overpayment in connection with this communication to our Deposit Account No. 11-1449.

Respectfully submitted,

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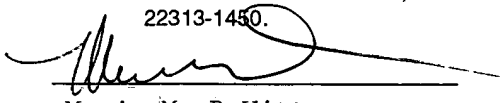

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